SIEMENS

# MODULARIS Uro Plus

SP

## Function Description

LITHOSTAR MODULARIS

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## The first step

This introduction provides an overview of the most important components of the MODULARIS Uro Plus system. It describes the function of the LITHOSTAR MODULARIS therapy unit and the MODULARIS Uro patient table.

The supplied operating instructions contain information on operating the system.
This chapter contains only the most important information.

The objective of this document is to describe all system functions, from the beginning of the function (e.g. via the manual control) to the end (e.g. motor starts running). Understanding all of these functions will provide faster service (shorter repair times).

An important issue which has emerged from the many courses on older LITHOSTAR systems, is the fact that it is essential to understand how the system should operate under normal conditions. This way, if the system should malfunction, it will be easier to recognize "what is different", and to come up with an appropriate strategy for troubleshooting.

## Components of a MODULARIS Uro Plus system

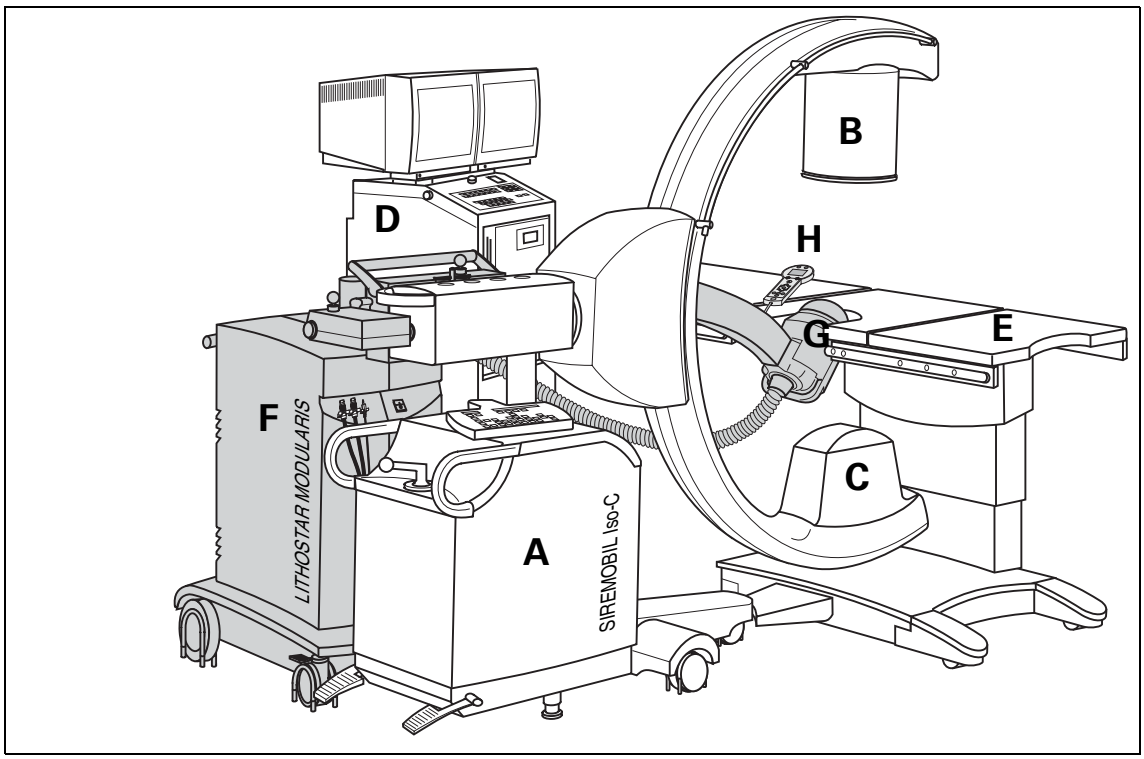



Fig. 1

**Imaging module:**

A: SIREMOBIL ISO-C basic unit with X-ray generator
B: Sirecon 23-3 HDR image intensifier
C: X-ray tube with integrated collimator
D: Trolley with monitor and Memoskop digital memory

**Table module:**

E: MODULARIS Uro patient table

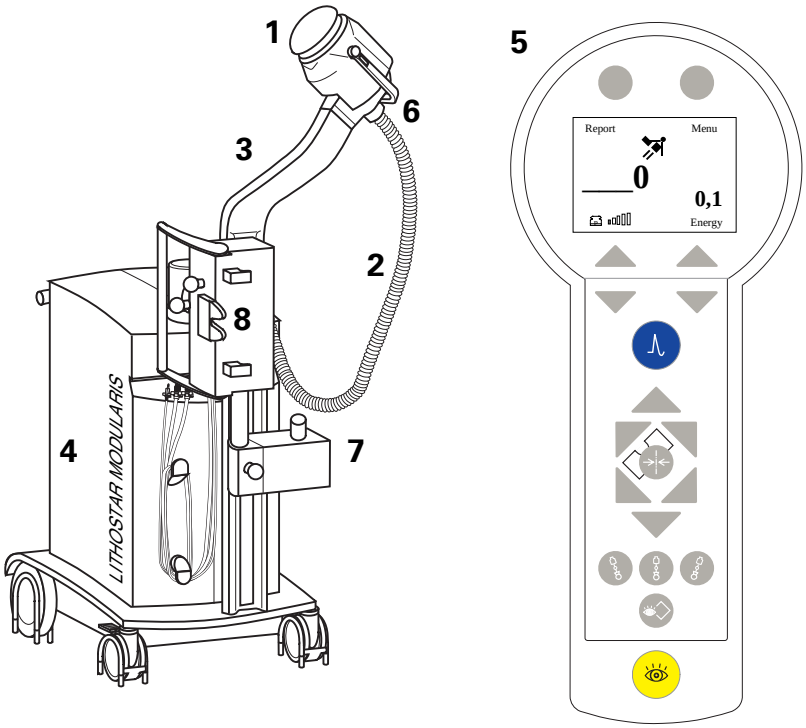
**ESWL module:**

F: LITHOSTAR MODULARIS
G: Shock wave head with shock wave system C
H: Manual control

**Options:** (not shown)

SIRECUST ECG triggering
SONOLINE Prima ultrasound device (general monitoring)
e.g. Multispot 2000 multi-format camera / laser camera connection)

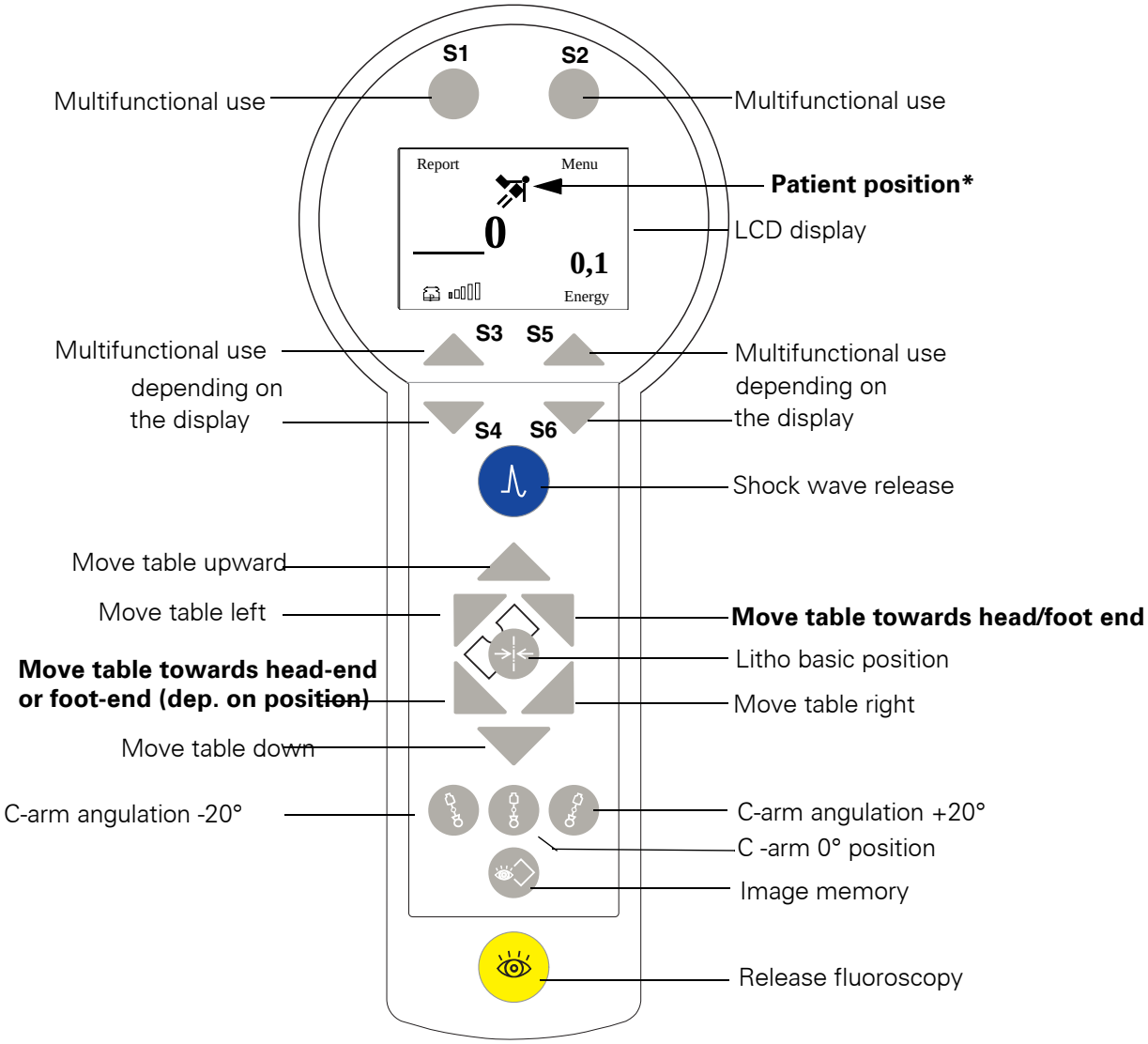
## LITHOSTAR MODULARIS overview




1. Shock wave head
2. Supply line
3. Support arm
4. Basic unit with
   - control unit with chip card reader
   - shock wave generator
   - cooling unit with hydraulic control
   - power supply
   - control cable to SIREMOBIL Iso-C
   - control cable to MODULARIS Uro table
   - control cable to SIRECUST ECG unit
5. Manual control with LCD display
6. Focus measurement device (focus phantom)
7. C-arm angulation motor (+/- 20 degrees)
8. Coupling and locking unit to the SIREMOBIL ISO-C

   Options: (not shown)
   - SIRECUST ECG triggering
   - ultrasound general monitoring

## Manual control with LCD display and selection keys

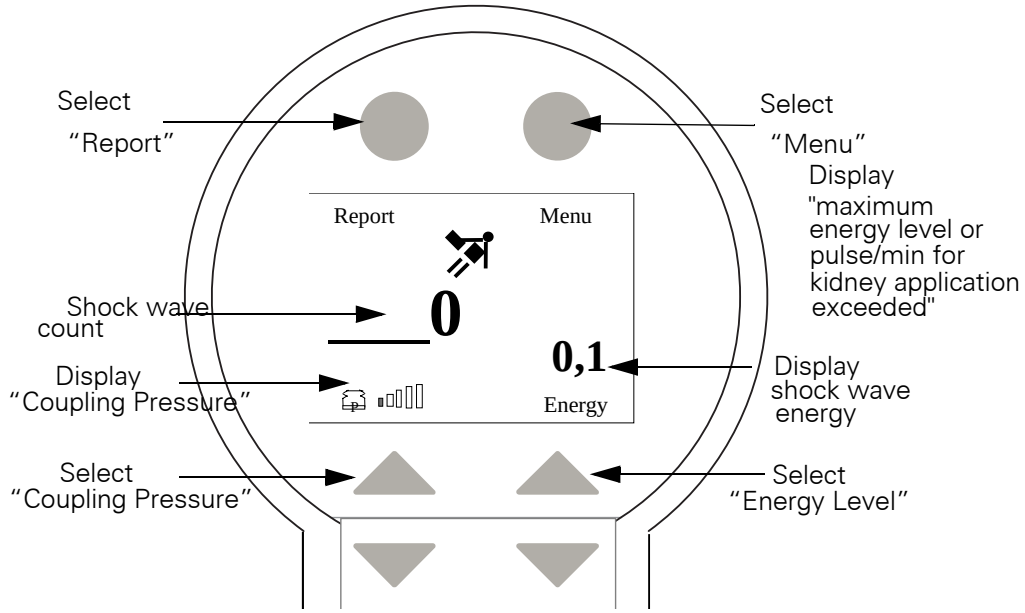



The manual control comprises the LCD display with buttons for controlling the shock wave system, and buttons for controlling the table movement or C-arm for localization. There are additional buttons for radiation release and image storage.

* Orientation: At the beginning of the treatment, the user determines the "patient position" in the display. The shock wave head is the point of reference. The travel direction of the table then depends on the kidney to be treated. Headward or footward can be reversed, depending on the table orientation.

## Menu displays

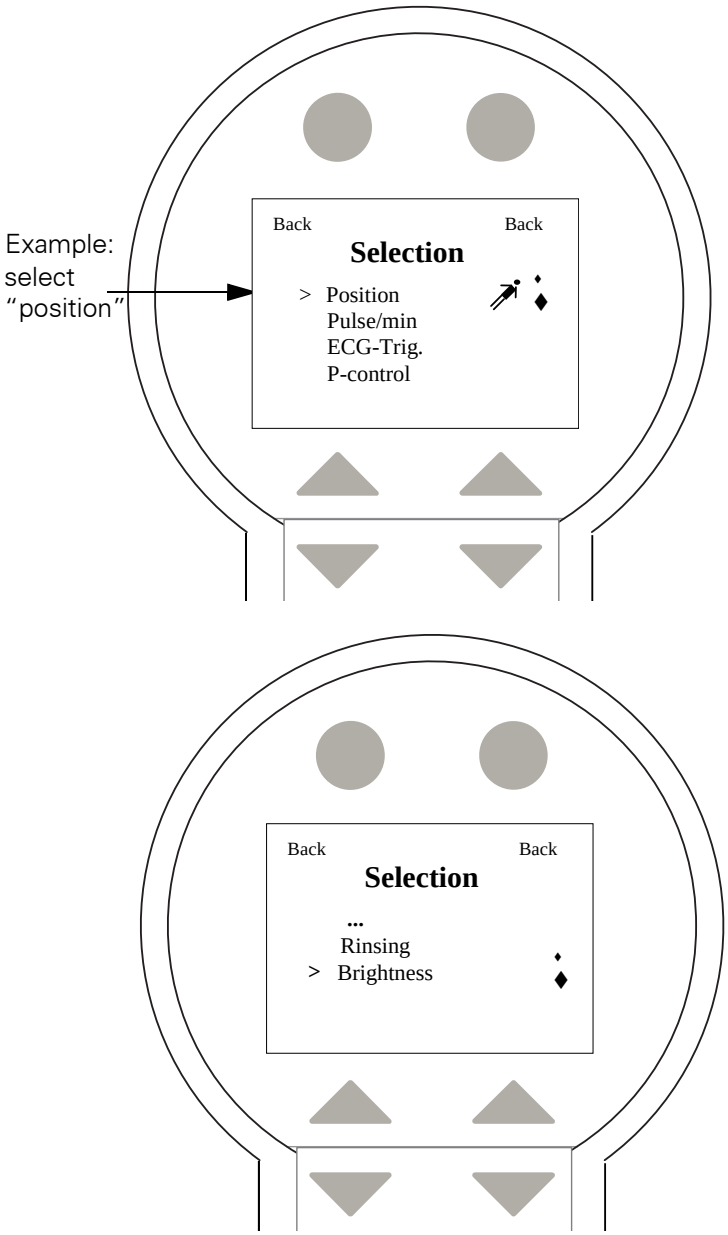
After system startup




Coupling pressure: 5 levels are selectable. Gel position if none are selected. Coupling pressure is continuously adjustable after switching to the selection menu.

Energy levels: selectable from 0.1 to 8.0. After level 4, a warning appears "kidney application exceeded!"

## Selection menu




The selection menu is used to select and set the parameters displayed above.

- patient position
- P regulation
- shock wave release frequency
- rinse coupling circuit
- ECG triggering
- brightness set (LCD display)

Refer to the next chapter for additional service-specific details on the menus.

## Using menus in the display

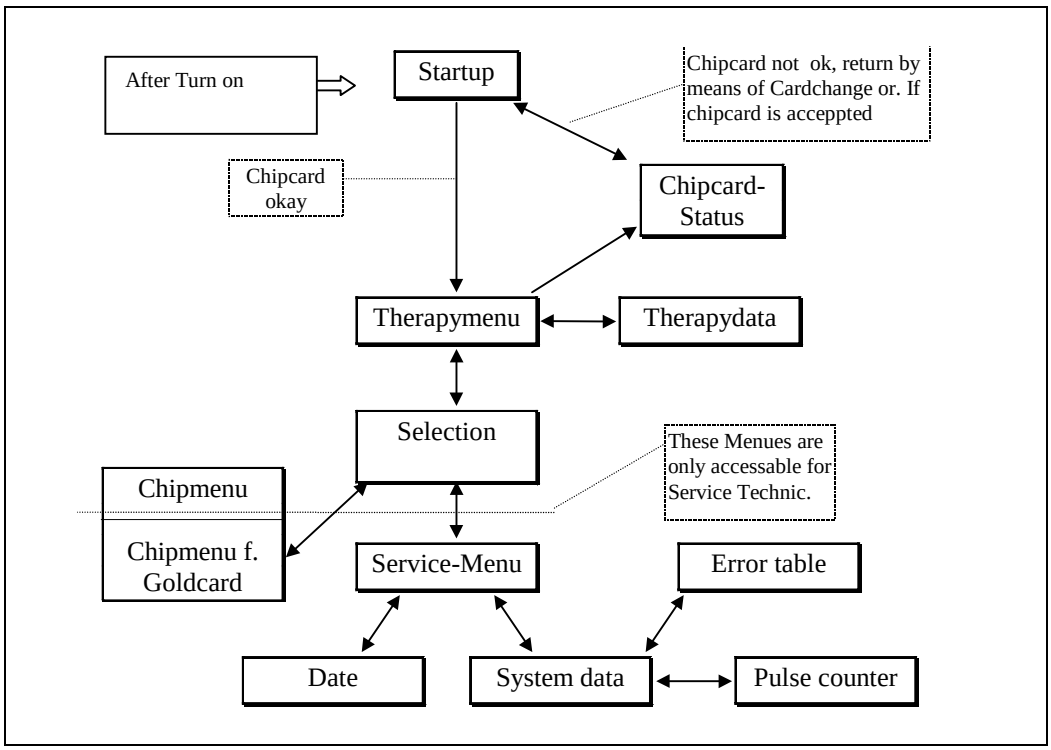



Fig. 1

Once the system successfully starts up, the therapy menu is displayed.
If this is a pay-per-use system, the user can access the chip menu in order to check the current chip data.
For Goldcard systems, the chip menu is only accessible in service mode.
(Service mode: switching S2 on board D3.)

## System start-up

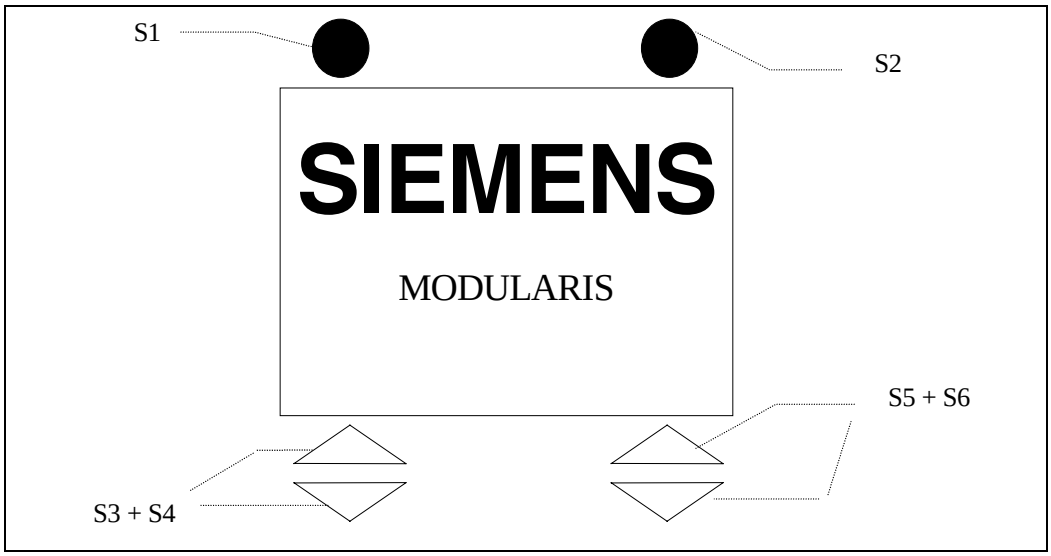



Fig. 2

If the system uses the Siemens configuration, the above will be displayed once the LITHOSTAR MODULARIS is switched on. The keys on the manual control unit are

blocked and cannot be activated until the start-up process is completed. After an automatic water circulation cycle in the coupling circuit (length of time approx. 18 sec), the chip card interface is checked. If the chip card is in order, the therapy menu will appear. If the chip card is empty, invalid, or defective, the user must take appropriate action (refer to chip card interface).

## The therapy menu

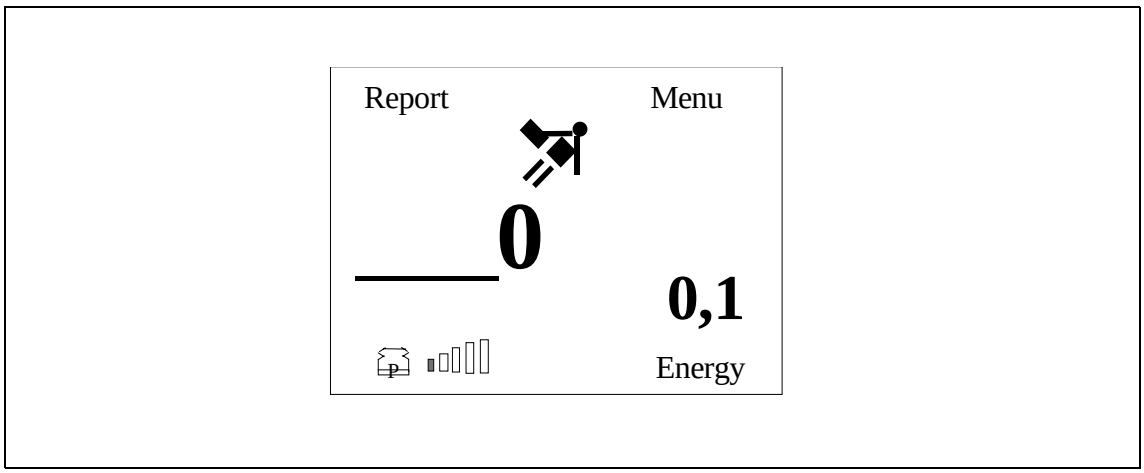



Fig. 3

## Functions:

- Increase or decrease the energy level (refer to shock wave system).
- Increase or decrease the coupling pressure (refer to shock wave system).

Report: Press this key to display the therapy data. Pressing the Reset key for more than one second resets the therapy data, and returns to the therapy menu.

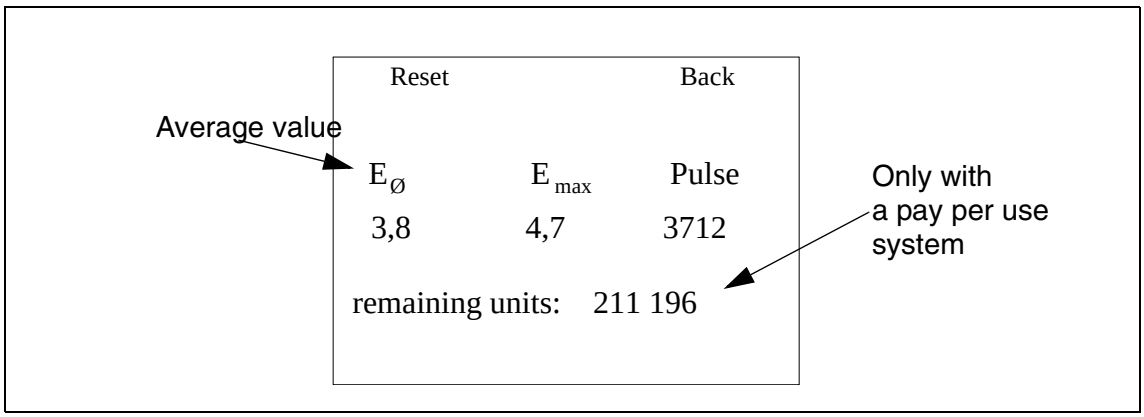



Fig. 4

## The selection menu

There are two display pages for this menu.

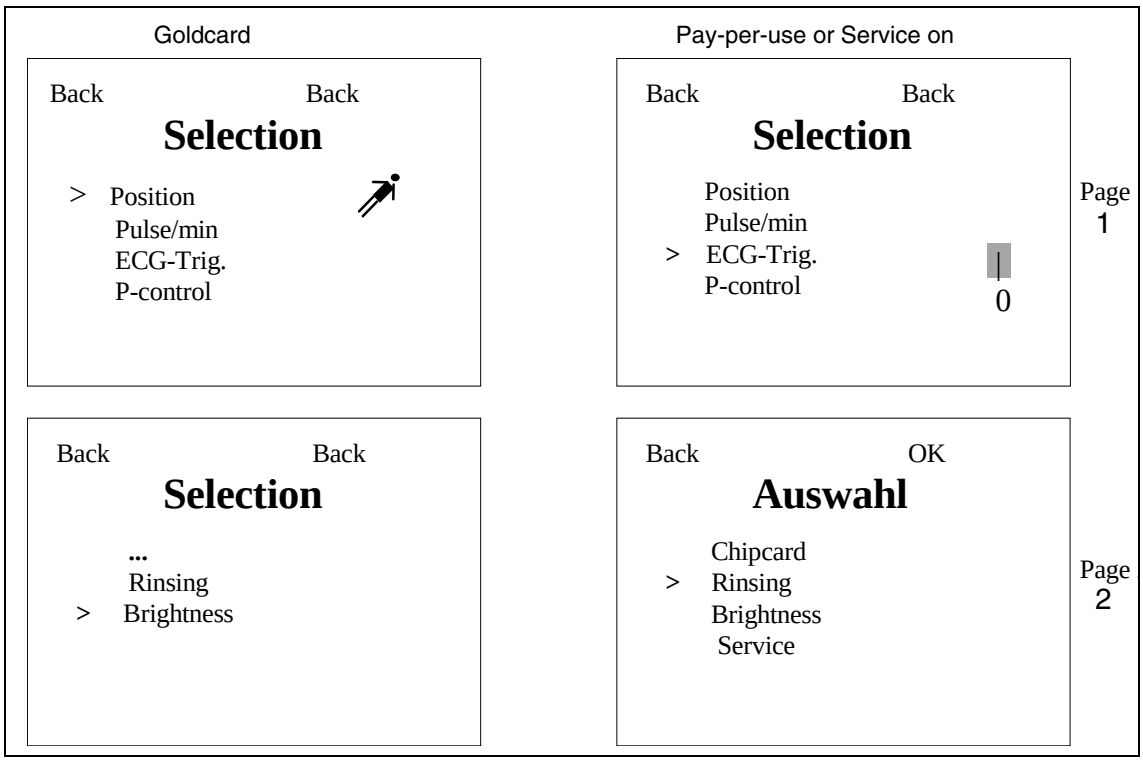



Fig. 5

## Functions:

- Pulse/min: 60/90120 shock waves per minute selectable (USA 2Hz fixed).
- ECG - triggering: select on/off (option).
- P-regulation: in steps or continuously selectable (refer to shock wave system).

The chip card menu depends on the chip card being used.

.

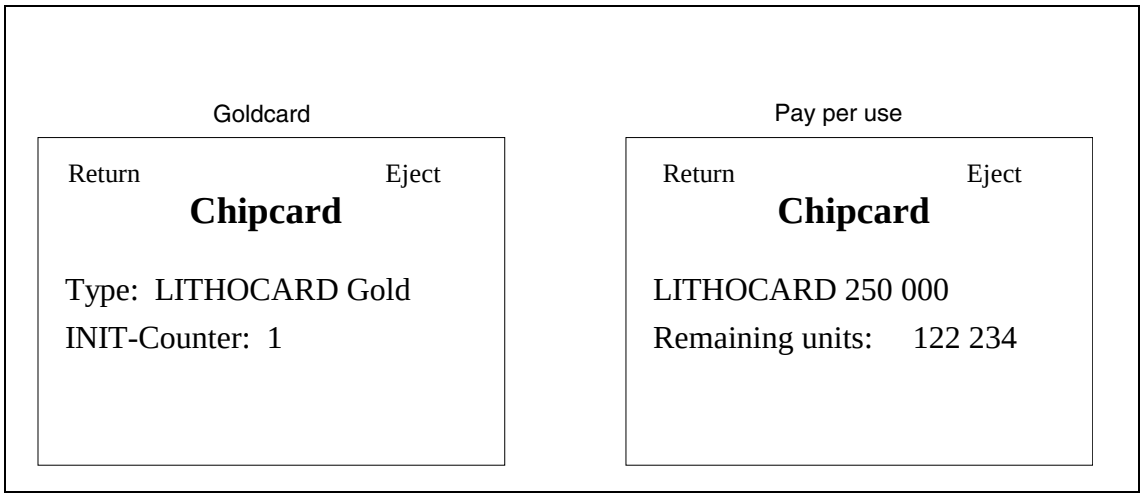



Fig. 6

Refer also to chip card interface.

## The service menu (English only)

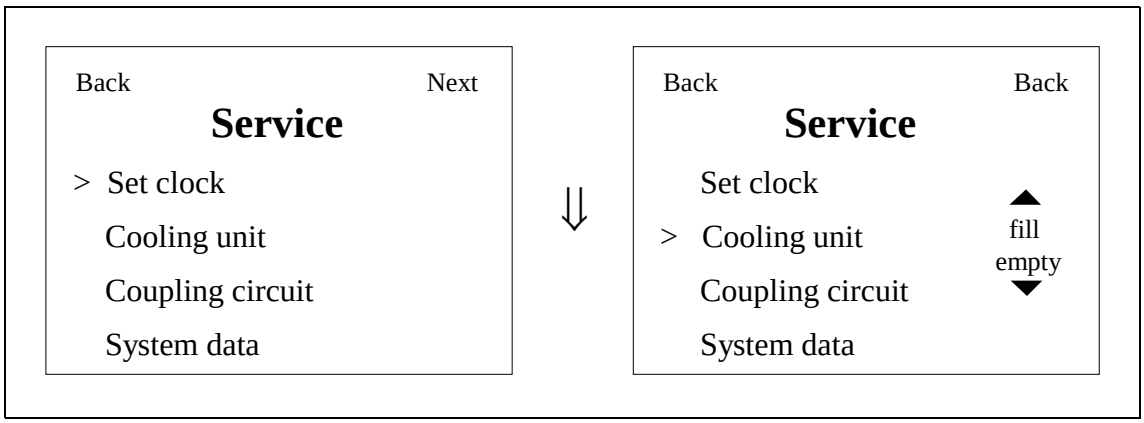



Fig. 7

Back returns to the "selection menu".

### Functions:

- Set clock: set the time and date. Refer to control board D3
- Cooling unit and coupling circuit: fill/empty the cooling circuit and the coupling circuit; use arrow keys to activate. Refer to shock wave system.
- System data: also refer to control board D3, shock wave system, C-arm angulation

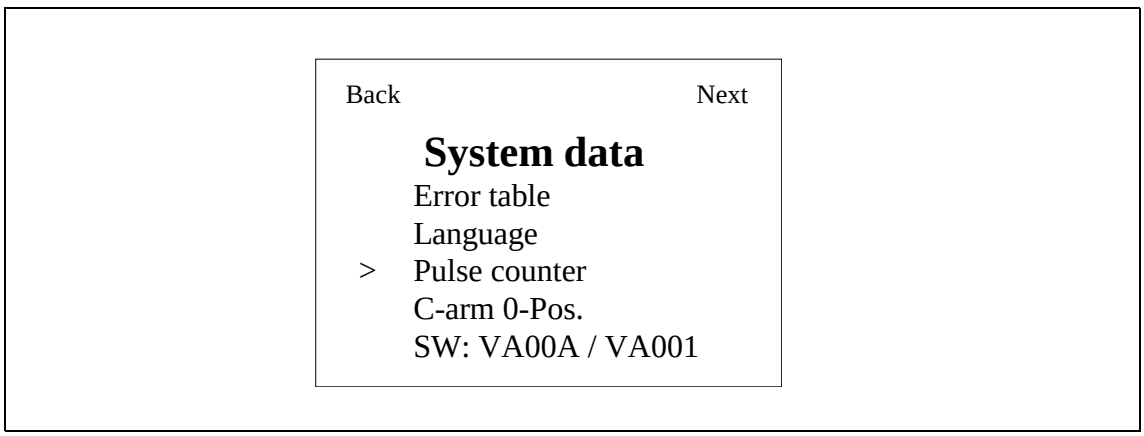



Fig. 8

Í Error log

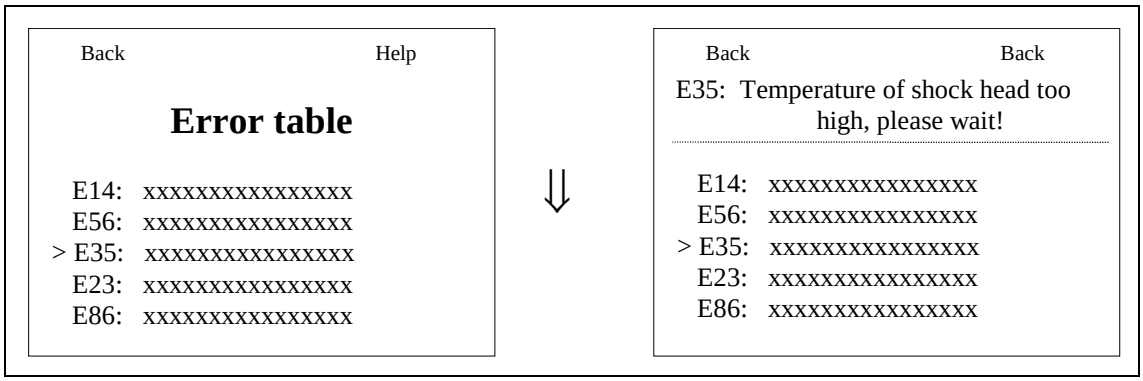



Fig. 9

The error log lists the errors in the order of their occurrence, with the most recent at the top of the list. Press Help for more detailed information. The last 100 errors are listed.

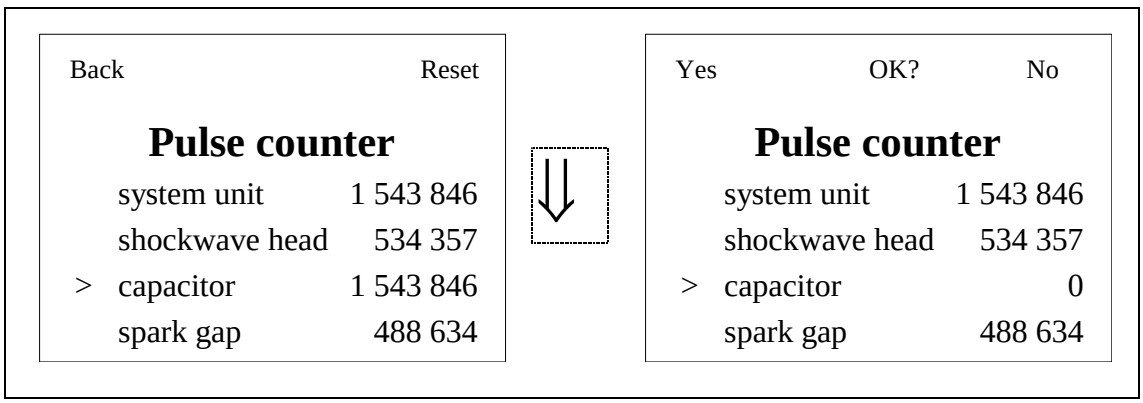



Fig. 10

Check the shock wave counter: displays the shock waves released with respect to the individual components of the shock wave system.

Reset procedure: after pressing the reset key, a reconfirmation query appears (yes/no).

The total shock wave counter (system unit) cannot be reset.

## Summary:

This chapter describes the most important system operations for service with respect to the **therapy, selection,** and **service** menu, and categorizes the various main functions.

- Í increase or decrease the energy level (refer to shock wave system)
- Í increase or decrease the coupling pressure (refer to shock wave system).
- Í Pulse/min: 60/90120 shock waves per minute selectable (USA 2Hz fixed).
- Í ECG - triggering: select on/off.
- Í P-regulation: in levels or continuously selectable (refer to shock wave system).
- Í Set clock : set the time and date (refer to control board D3)
- Í Cooling unit and coupling circuit: filling or emptying the cooling circuit and the coupling circuit, activated via the arrow keys (refer to shock wave system).

The main functions of the system will now be illustrated and discussed using a block diagram.

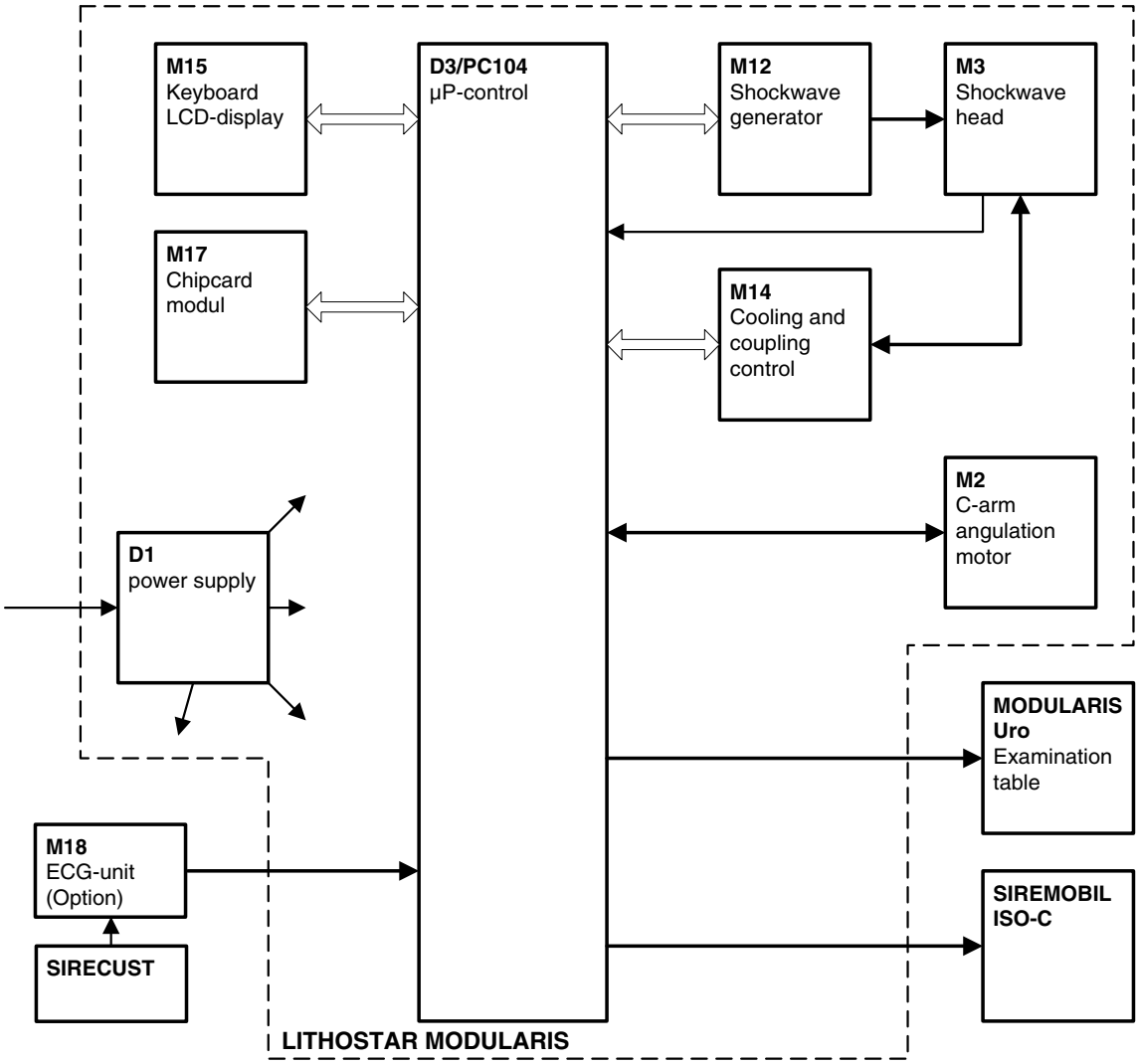
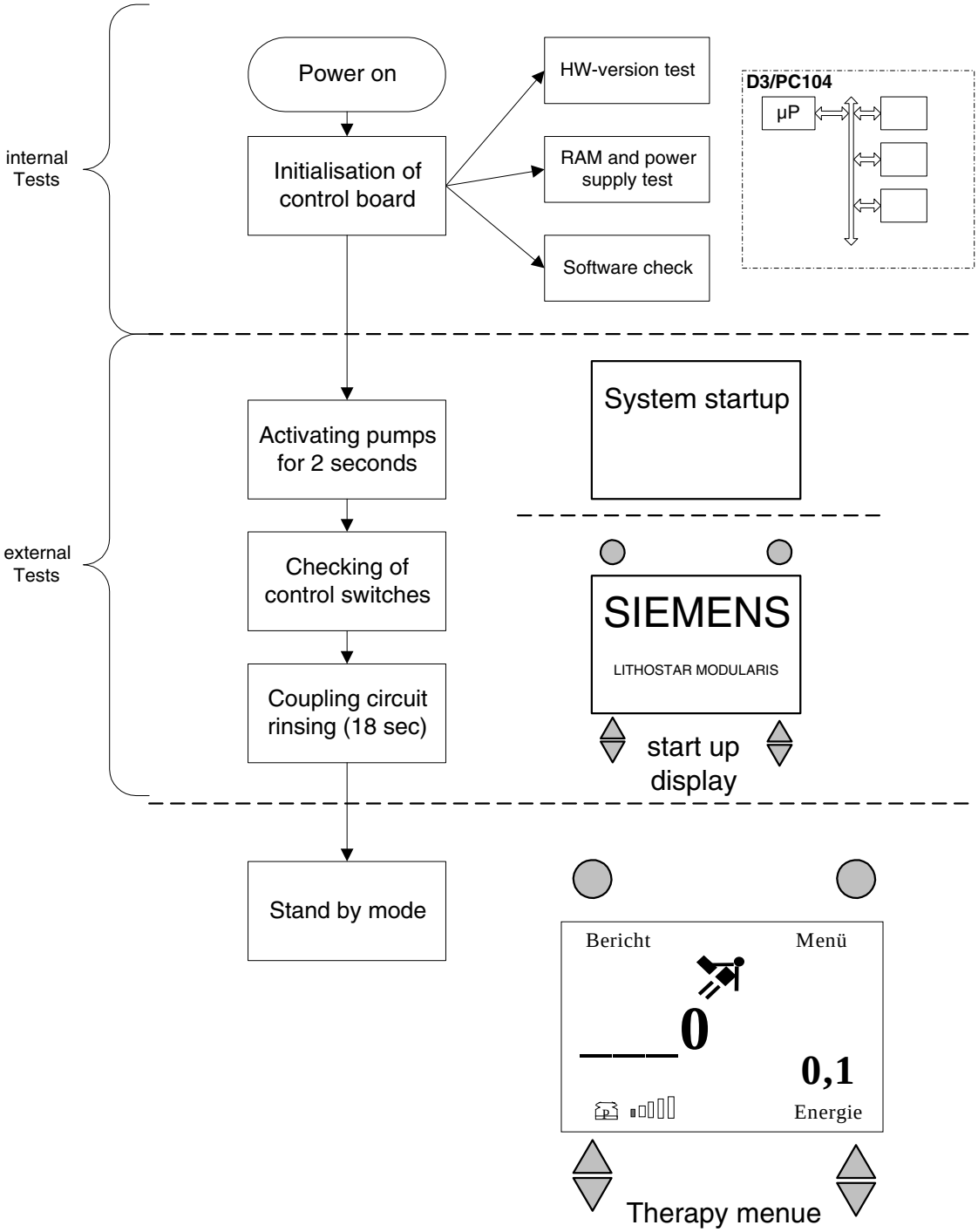



Fig. 1 Block diagram of the LITHOSTAR MODULARIS

## Main system functions

- The operating and menu functions (already discussed in chapter 2 ) are extremely important, since they affect almost all of the system functions. Location is M15 and controller D3/PC104. The PC104 piggy-back board realizes a PC-based system.
- The main function of the system is to generate a shock wave starting with the release key, and up to the point where the shock wave enters the patient's body.
  Components involved are: M15, controller D3/PC104, the shock wave generator with high voltage generation M12, the shock wave head M3, the cooling and coupling system M14, and M18 for ECG-triggered shock waves with the SIRECUST.
- Stone localization in the urological tract is achieved via motorized movement of the C-arm M2 and the MODULARIS Uro table.
  The imaging system is the SIREMOBIL ISO-C (FL or DR, etc.).

- The chip card module enables "pay per use" operation; in other words, it contains a certain number of shock waves which the user can release. A goldcard system is also available. The chip card module is covered, so that the card is not accessible from the outside.




## Internal tests (initialization)

After switching on the software initializes the internal register, counters, I/O ports, interface circuits, etc. The system also checks the validity and functionality of the hardware and software versions, the power supply, the memory circuits, the user software, and much more. It also initializes the manual control.If an error occurs during this phase, an error message will appear on the 7 segment display on the control board. Immediately after switching on the system, the manual control displays "system start-up".

## External tests

During this phase of the start-up process, the manual control displays **"start-up display"**. To tear off (start up) the cooling and coupling circuit pumps, they are switched on for approximately 2 seconds. Then the program activates the water circulation cycle in the coupling circuit, which takes approximately 18 seconds. This procedure removes any air bubbles which may be present in the coupling bellows.

The **"therapy menu"** is displayed, indicating that the system start-up is complete. If there are no more activities, the system is in normal mode.

In normal mode, the processor system checks functions such as:
power supply, correct pump function, water temperature and water pressure, etc. Any errors will be displayed on the manual control display.

## Start-up after download and new control board D3

The service switch on D3 is set to "on". After approximately 20-30 seconds, "0" is displayed on the 7-segment display. The switch-on message is "E00".

The following error messages are normal:

E53,E80,E81,E82,E83,E86 internal data invalid, initialized at the first start-up.

These messages will no longer appear once another reset is performed, and the system will start normally, as described above.

## Overview

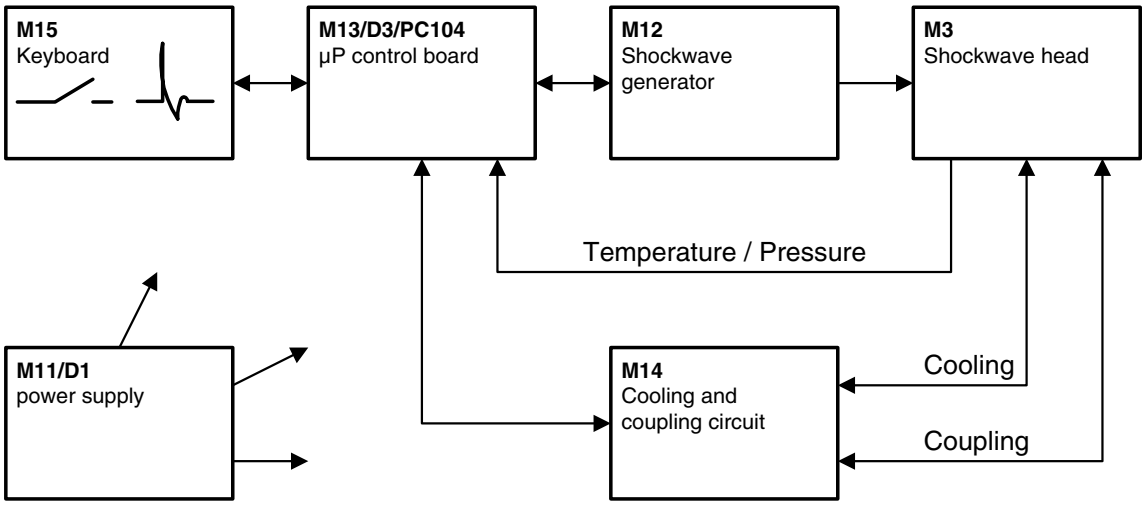



Fig. 1 Circuit diagram of the shock wave system

The shock wave system comprises the following components:

- the shock wave components M12 and M3.
- the cooling circuit M14.
- the coupling circuit M14.
- the controller D3/PC104
- the release switch on manual control M15.

The objective is to generate a shock wave in shock wave head M3, which then enters the patient's body. The stone must be positioned in the focus of the shock wave head, and is fragmented as a result of the shock wave pressure.
**Shock wave generation** is based on the electrodynamic principle. The discharge current of a 1.2 µF capacitor flowing in a primary coil causes the metal membrane in the secondary coil to deflect in the axial direction. This creates an acoustic wave which is focused via a synthetic lens.
The shock wave passes through a water-filled coupling bellows and then enters the patient's body. The water pressure and flow rate determine optimal coupling. The water pressure in the **coupling circuit** is constantly monitored.

Generating shock waves creates heat which must be cooled via a **cooling circuit** so that the coupling water does not overheat and burn the patient's skin. Furthermore, the static and dynamic water pressure in the cooling circuit presses the metal membrane (secondary coil) onto the primary coil, in order to provide optimized energy transfer.
The shock wave intensity is varied (pressure at the focus) in the primary coil of the shock wave head.

## (The shock wave head

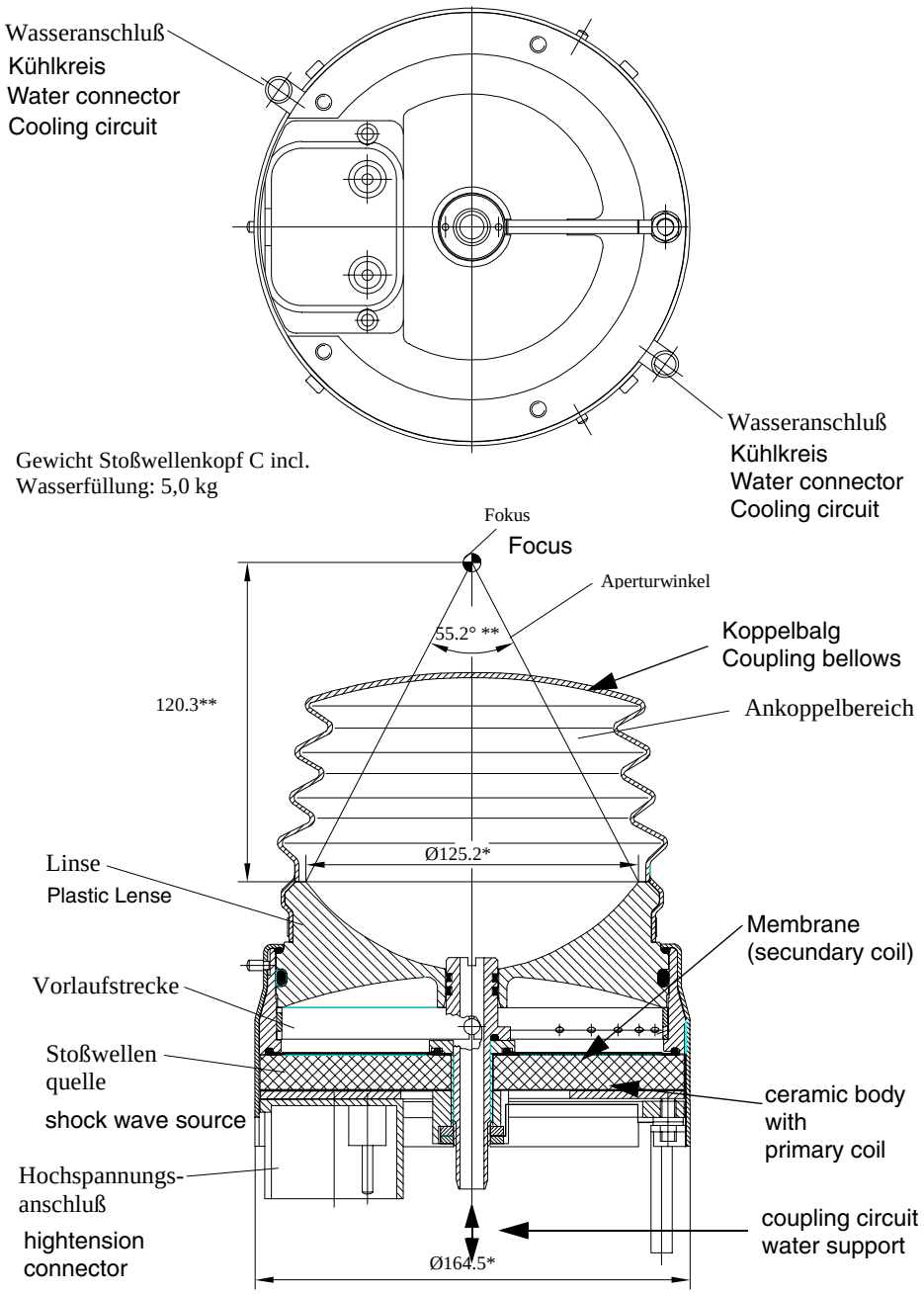



Fig. 2 Layout of the shock wave head and coupling bellows (does not correspond to the original MODULARIS shock wave head)

## The cooling and coupling circuit hydraulics

**Fig. 2** shows the principle construction of the shock wave head. The following provides additional information on the shock wave head with respect to the cooling and coupling circuit.

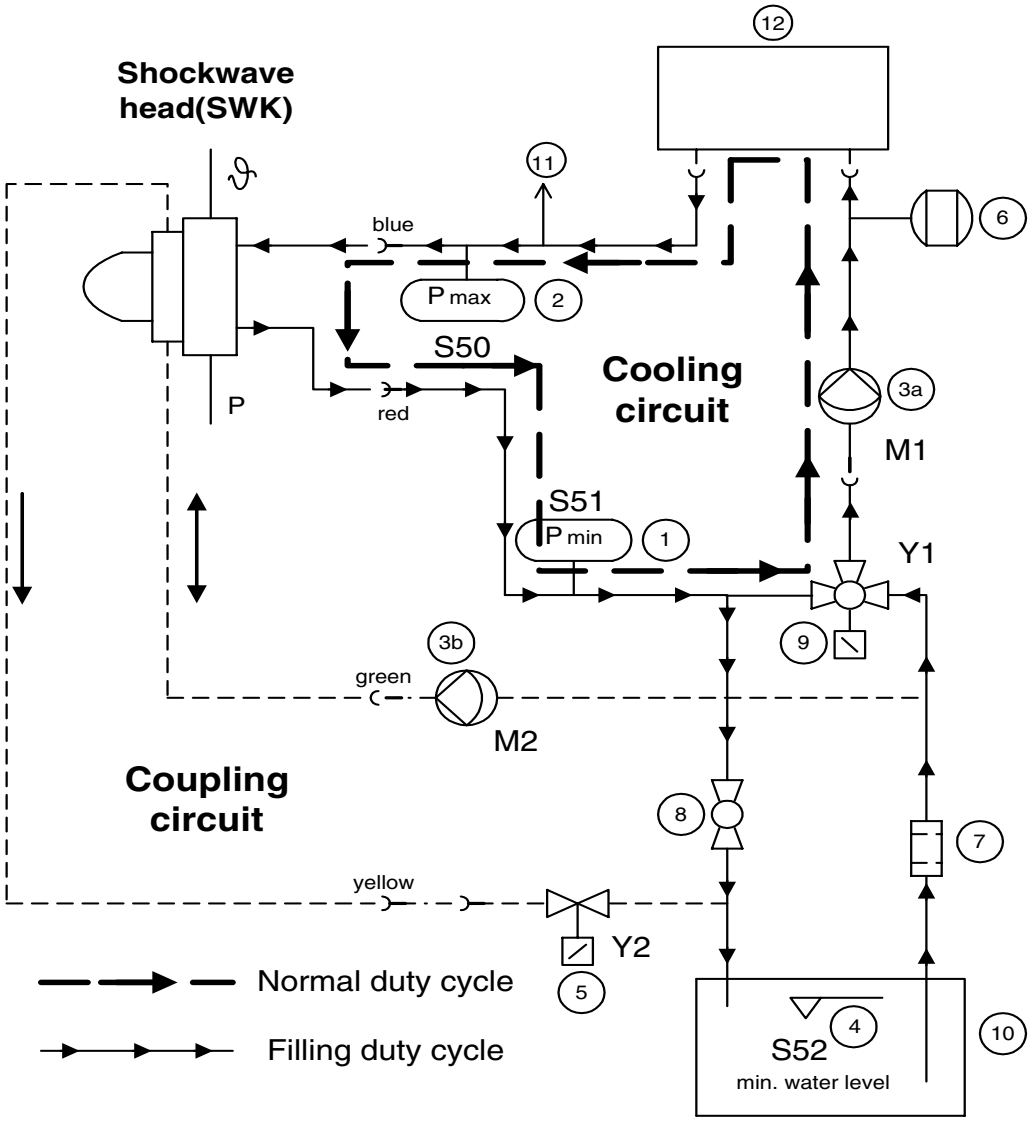



Fig. 3 Circuit diagram of the cooling and coupling circuit

| | | | |
|---|---|---|---|
| 1) | Druckschalter/Pressure switch (p min) | 6 | Druckausgleichsbehälter / Pressure balance container |
| 2 | Druckschalter /Pressure switch(p max) | 7 | Wasserfilter / Water filter |
| 3a | Schlauchpumpe / Peristaltic pump (Cooling circuit) | 8 | Kugelhahnventil / Ball valve (emptying cooling circuit) manual |
| 3b | Schlauchpumpe / Peristaltic pump (Coupling circuit) | 9 | Magnetventil / Solenoid valve (Filling cooling circuit) |
| 4 | Schwimmerschalter / Floating switch | 10 | Wasserbehälter / Water supply |
| 5 | Belüftungsventil / Degassing valve (Coupling bellows) | 11 | Entlüftungsventil / Degassing valve |
| | n.a. | 12 | Kühlgerät / Cooling unit |

## The cooling circuit

**Objective:**

- to cool the shock wave source; the water temperature in the coupling system may not exceed 41°C under any circumstances.
- to generate static water pressure in the cooling circuit, which presses the membrane (secondary coil) against the primary coil (embedded in the ceramic body), in order to provide optimal energy transfer.
  **Note:** The shock wave head is designed so that the water flow causes dynamic pressure to build up, therefore supply and return hoses must not be interchanged.

For **temperature monitoring**, two temperature sensors enclosed in a metal housing are pressed against the ceramic body of the shock wave head by a compression spring. Controller board D3 monitors the signal forwarded via an A/D converter in the µP microprocessor-controlled system.
The cooling circuit pump switches on:
"with the start of shock wave release, or if the temperature is too high".

| Temperature | cooling pump |
|---|---|
| Temp<5°C | release blocked, error message "Sensor defective" |
| 5°C<Temp<40°C | cooling pump on: velocity 60% |
| 40°C<Temp<60°C | cooling pump on: velocity 70% |
| 60°C<Temp<80°C | cooling pump on: velocity 80% |
| Temp>80°C | cooling pump on: velocity 80%, shock wave release blocked, error "shock wave head overheated |

**Function: (refer to Fig.3/5-3)**

**Normal mode:** the peristaltic pump **3a** forces the warmed water coming from the shock wave head (SWK) through the cooling unit **12** and then back through the shock wave head, etc. The pressure balance container **6** equalizes the pressure variations in the cooling circuit. Pressure switches **1** and **2** monitor the acceptable pressure values.
Degassing valve **11** removes small air bubbles from the cooling circuit.
If the maximum pressure (780mbar) is exceeded for more than 3 s, the µP sends an error message. If the minimum pressure is not reached, the 3-way valve 9 will switch to fill for 1s. In other words, water flows from water supply 10, through water filter 7, into the cooling circuit. After a pause of 2s, the µP checks the min switch. If the switch is not activated yet, the filling process repeats, otherwise the filling process is completed. If the minimum pressure is still not reached after 20 fill processes, the µP emits an error message: "leak in system".

**Filling and emptying:** "possible in service mode only"
Ball valve **8** must be opened manually. In the service menu, select either fill cooling circuit or empty cooling circuit. 3-way valve **9** switches over. Activate the pump via the manual control. During the filling process, pump water into the cooling circuit until there are no more air bubbles visible in the water return. The pump stops if the pressure switch reaches max **2**. If the pressure switch responds while the circuit is emptying, the pump will continue to run.

## The coupling circuit

**Objective:**

The shock wave passes into the patient's body via the flexible front part of the shock wave head; the coupling bellows. It is extremely important that contact with the patient's skin surface is not interrupted, and that there are no air bubbles (due to total reflection).

Coupling can be done manually or automatically in five pressure levels, and is selected via the manual control. Automatic means that a pressure sensor monitors the working range of the selected pressure level and regulates the water fill in the coupling bellows.

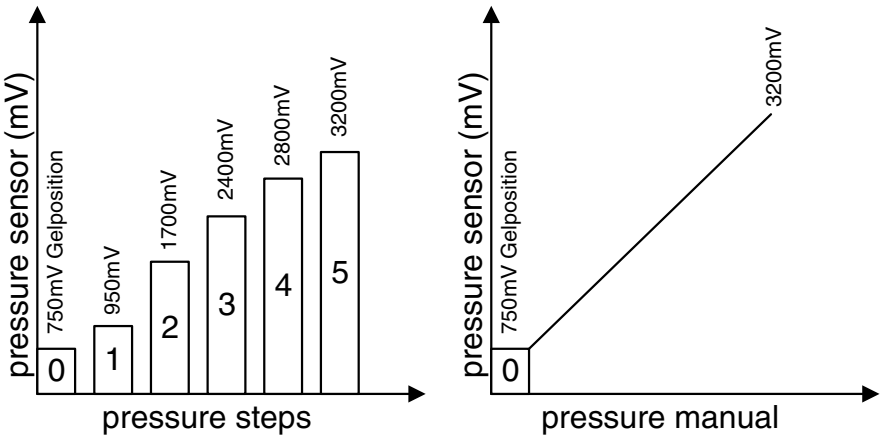



Fig. 4 Pressure levels selectable either continuously or in 5 levels. (pressure sensor output values in mV)

**Function: (refer to Fig.3/5-3)**

**Normal mode:** If automatic mode is selected, the peristaltic pump **3b** pumps water into the coupling bellows until the selected pressure level is reached (fill level of the shock wave head).
In manual mode, the user selects the fill level of the coupling bellows by activating the appropriate keys on the manual control. Pressing the key longer than 3 seconds changes the pump velocity from v1 to v2.
When the water supply is pumped out, the electronics switch off the pump and an error message is transmitted. Degassing valve **5** is closed.
Note: "rinse the coupling circuit" can be selected via the manual control. This removes air bubbles from the coupling bellows.

**Filling and emptying:** "only in service mode"
During filling, peristaltic pump **3b** pumps via water filter **7**. Degassing valve **5** is opened. The filling process is completed when no more air bubbles are visible in the return. A small hose is located in the coupling bellows, which is attached to the coupling bellows and suctions out air bubbles.
Emptying follows the same principle; the motor is reversed and water is suctioned out.

## Electrical circuit diagram of the cooling and coupling circuit:

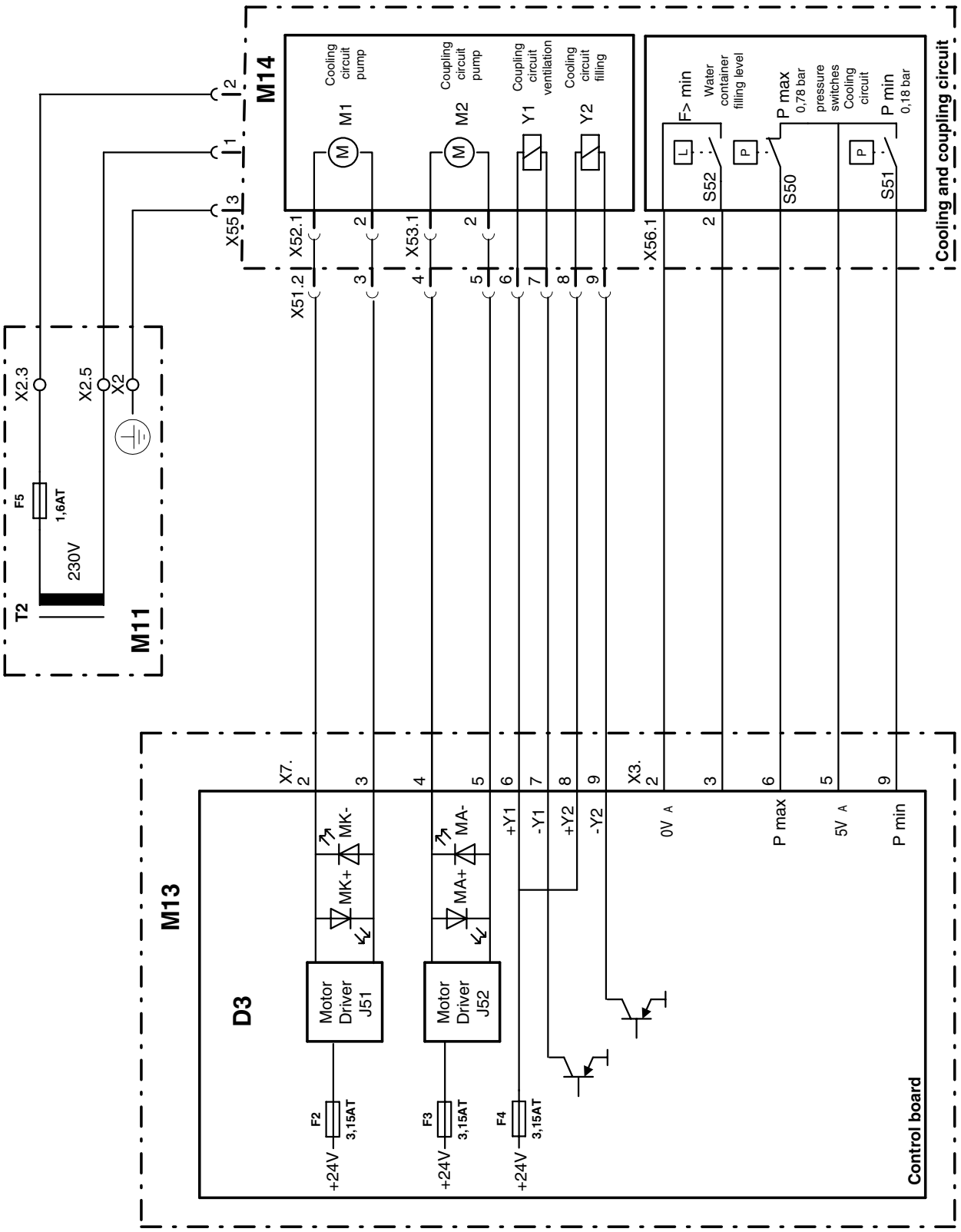



Fig. 5 Circuit diagram of the shock wave system

**M1, M2:** The two 24V pump motors are controlled via pulse-width modulation. That is, motor output can be controlled between 0% and 100%.
The temperature, control, and starting current are monitored.---> refer to error messages.

**Startup:** Via the motor drive, the µP switches on pumps M1 and M2 at 100% for 2 seconds.
After that, M2 runs for 18 seconds at 70% in order to remove air bubbles from the coupling circuit (only in normal mode).This time is omitted in service mode.

**Fuses F2, F3, F4:** are monitored by the µP system.

**Displays: MK+, MK-, MA+, MA-** clockwise or counter-clockwise.

**Measurement points:** n.a.

## The charging and high voltage circuit

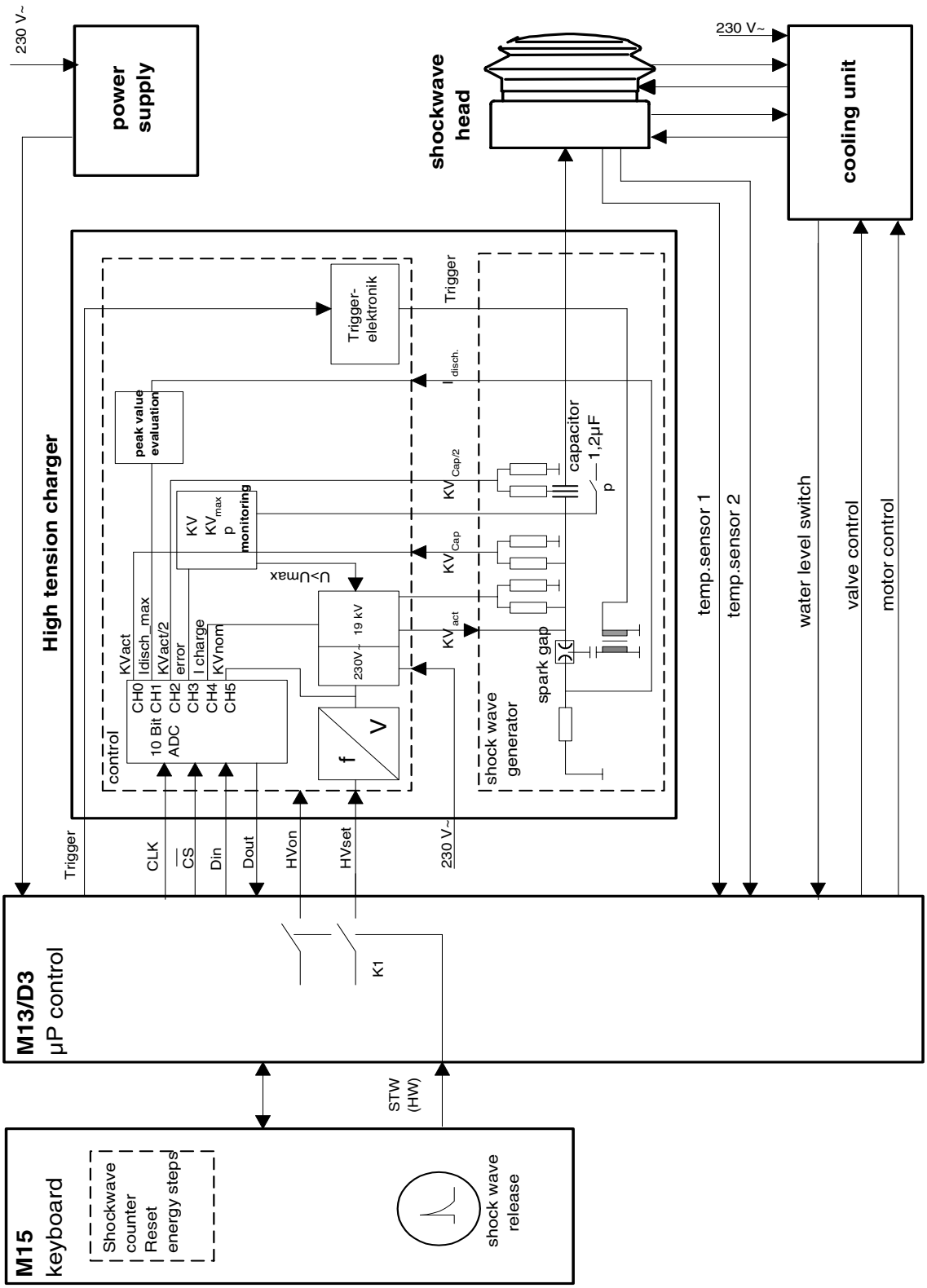



Fig. 6 Circuit diagram: high tension charger and discharge circuit

**Function: (refer to Fig.6/5-8)**

Prior to releasing a shock wave the following parameters must be set via the manual control:

**energy level** **release frequency** **ECG triggering on/off**

For "pay-per-use" systems, a valid chip card must be available.

The shock wave release key on manual control M15 activates relay K1 on controller board D3. There, the switch signal is coupled with the hard-wired software-controlled process. This provides added protection against unintentional shock wave release in cases of malfunction.

**Objective:** charging the 1.2µF capacitor in the shock wave generator with the energy level corresponding to the KV value, and then discharging it via the primary coil of the shock wave head.
The **HVon** (high voltage on) and the frequency coded **HVset** (nominal KV) begin the charging process (charge start). The **1.2 µF capacitor** is charged to this nominal value. Control D3 constantly monitors the KV nominal voltage via the A/C converter. The charging process is complete when the KV nominal value is reached.

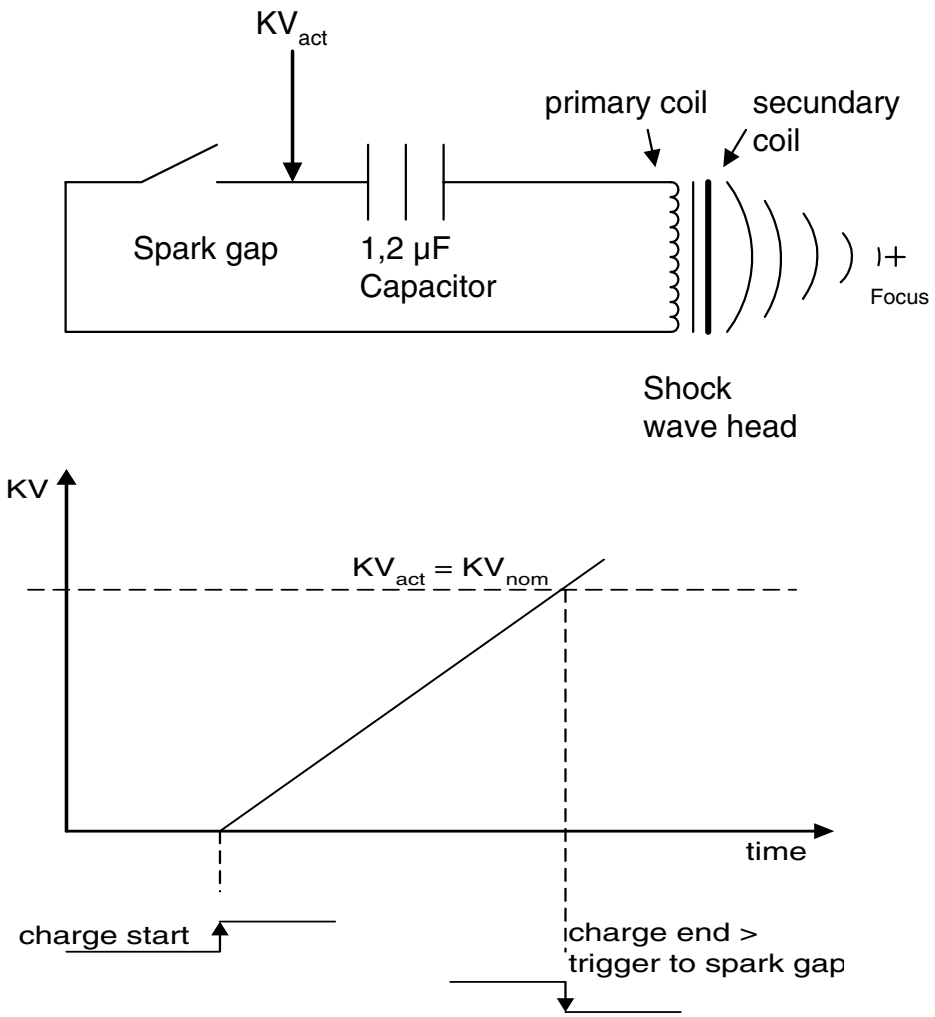



Fig. 7 Shock head and charging principle

Control board D3 now begins the discharge process, and generates a trigger signal to ignite the spark gap. Its function is similar to an electrical switch. During the above-described charging and discharging process, control board D3 constantly monitors such important parameters as:

- the total capacitor voltage **KVact**
- half of the capacitor voltage **KVact/2**
- the charging current **I charge**
- the discharge current **I discharge**

Using these values, the µP immediately recognizes a short in the capacitor, a loss in capacitance or an error in igniting the spark gap.

**Special note:**
After 500 shock waves, the µP automatically stops the release, in order to remind the user to check the focus. Continuation is only possible by opening and closing the release switch.

Shock wave release is interrupted when exiting the main menu.

The energy level value ranges from 0.1 to 8.0. The maximum required energy for treatment of the kidneys is 4.0; therefore a warning appears on the display for levels above this value. The auto-repeat function is not available between 4.0 and 4.2.

In free-running mode , the shock wave frequency can be set to 60, 90, and 120 pulse/min. In the kidney area, the frequency can be set only up to 90 P/min. If 120 P/min is set, it will be automatically reduced (fixed to 120 P/min in the USA).

In service mode, the release rate is limited to 15 shock waves/minute, and a chip card is not required.

The ECG triggered shock wave release depends on the patient's QRS signal. The shock wave is released when the heart muscle enter the diastolic phase. The release rate must not exceed the set free-running rate.

If a QRS signal is no longer detected for more than 2 seconds, the system will emit an error message.

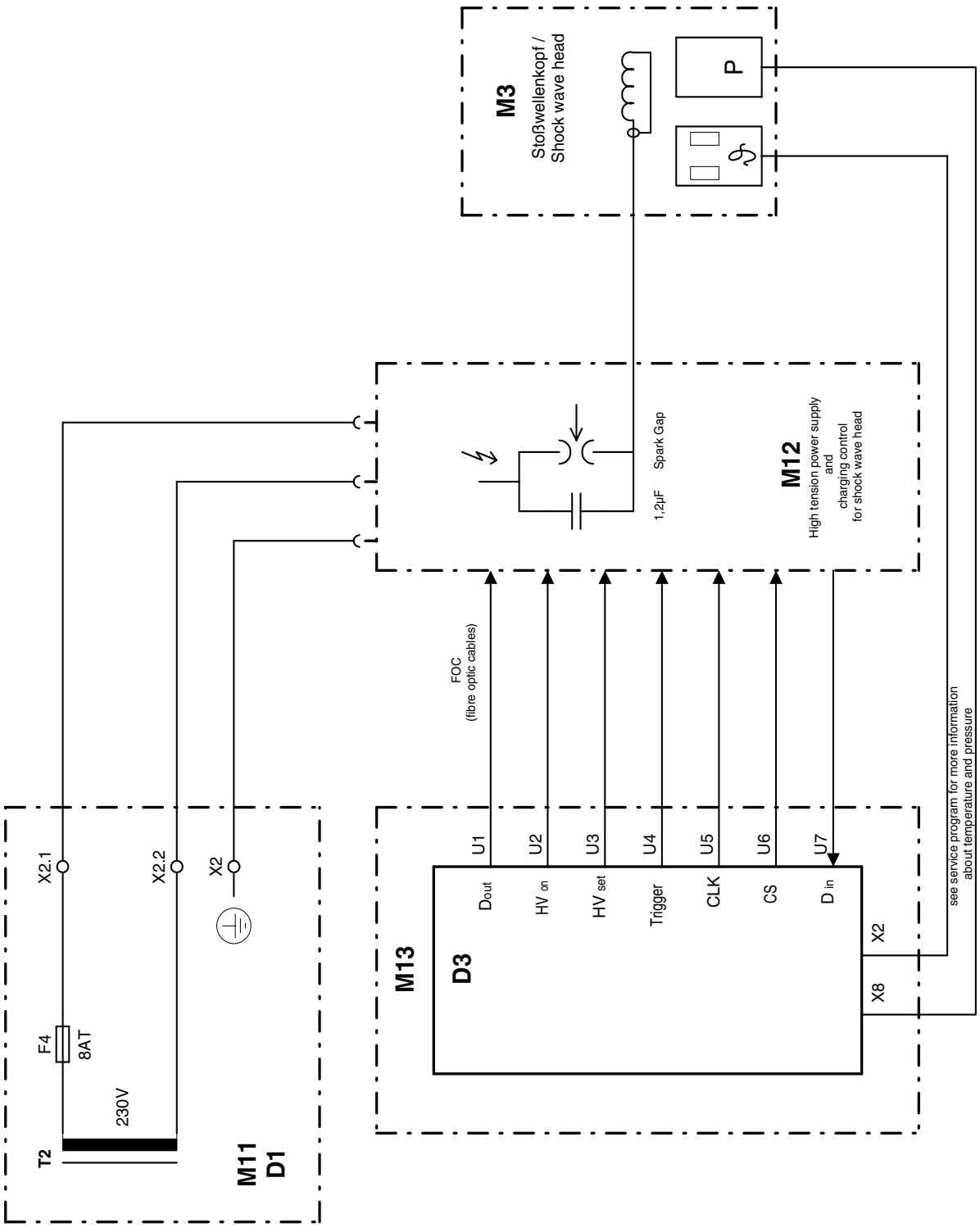



Fig. 8 Circuit diagram of the charging / energy unit

## Interface between D3 and M12

The control signals between D3 and M12 are galvanically separated by routing them via fiber optic cables. "Active high" indicates that the transmission diode (LED) for the receiver is active.> LED on

**Explanation (with respect to M12):**

**Input**

| | |
|---|---|
| HV on: | switch-on signal for the charging current circuit; high voltage on; LED on |
| HV set | nominal voltage frequency encoded; (1KHz = 1 KV) max 19.3 KV |
| Trigger | trigger pulse to the ignition transformer; LED on |
| CLK | synchronization of A/C converter and µP system |
| CS | chip select; start A/C conversion; LED on. |
| D in | data input A/C converter |

**Output:**

| | |
|---|---|
| D out | data output A/C converter. |

**General:**
For the charging/energy unit, only the spark gap can be replaced; all other malfunctions require a complete replacement.

## Overview

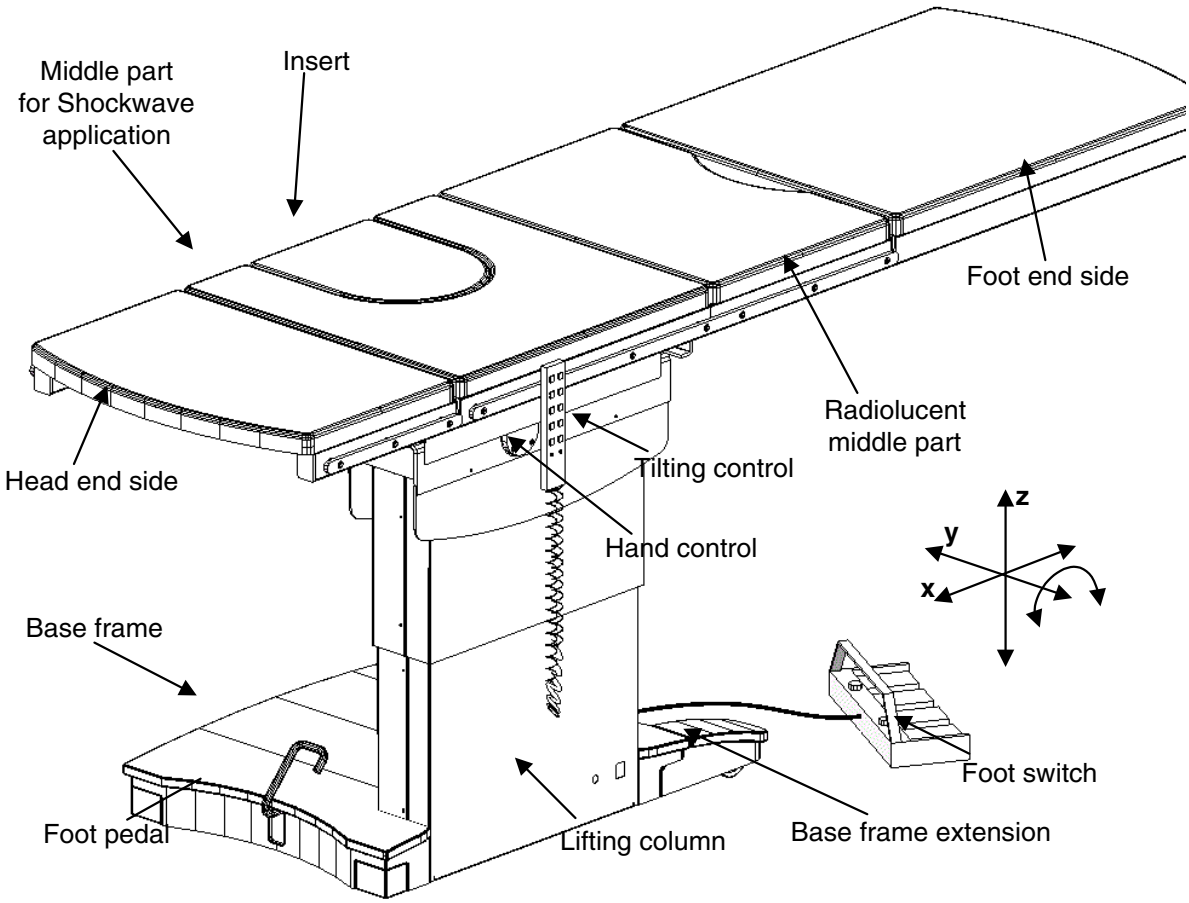



Fig. 1 Overview of table operation

**The MODULARIS Uro patient table is used for the following medical applications:**

- urological diagnostics and endourology
- extracorporeal shock wave lithotripsy
- prostate therapy

**Four movement axes are available for positioning the patient:**

- patient table toward the head-end, foot-end
- transverse patient movement
- upward and downward movement
- table tilt

## Manual control

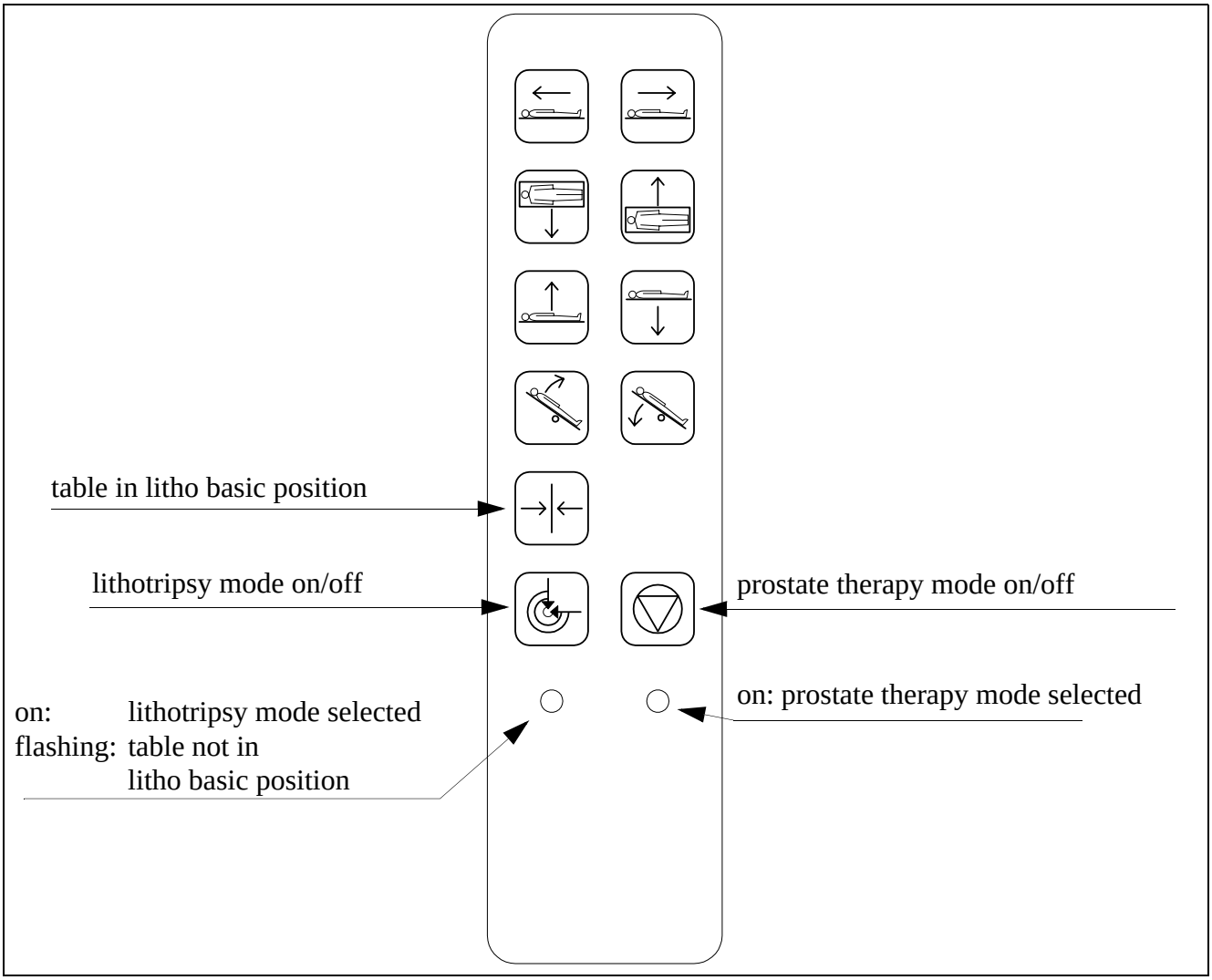


table in litho basic position
lithotripsy mode on/off
prostate therapy mode on/off
on: prostate therapy mode selected
on: lithotripsy mode selected
flashing: table not in
litho basic position

Fig. 2 Overview of patient table operation

**Lithotripsy mode on/off:** the system limits the table's range of motion, due to the fact that in the working position, the shock wave head could collide with the tabletop. Millimeter step mode is also possible in this operating mode .

**Litho basic position:** After selecting the lithotripsy mode, pressing this key causes the tabletop to move into the basic position. The display light flashes until the basic position is reached. The same key is also on the LITHOSTAR MODULARIS manual control. As long as the LED is flashing, the basic position is not reached yet.

**Prostate therapy mode:** all table movements are blocked in this operating mode.

## Interface between LITHOSTAR and patient table

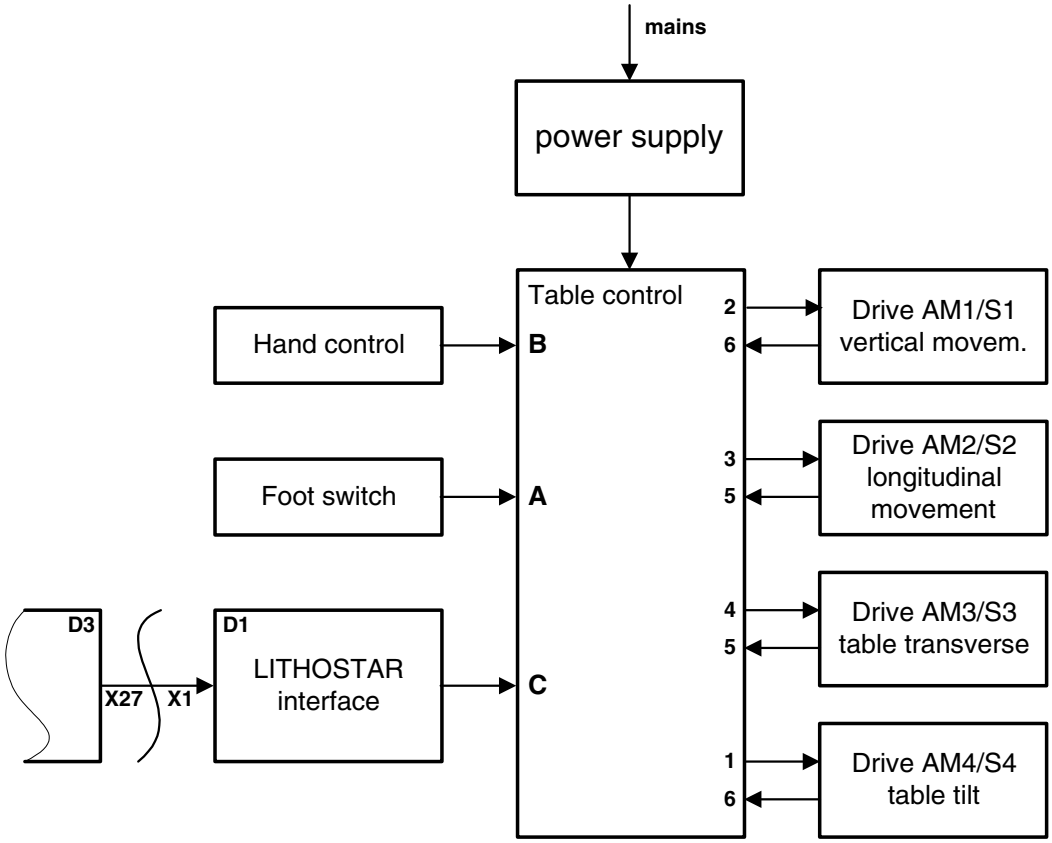



Fig. 3 Block diagram of table control

The patient table movement is controlled with the LITHOSTAR MODULARIS manual control via the connection **X27-X1 from D3 to D1**.
The signals for the table movement for each axis (one motor) are encoded via two logical lines.

| Line 1 | Line | Movement |
|---|---|---|
| 0 | 0 | stop |
| 1 | 0 | forward |
| 0 | 1 | backward |
| 1 | 1 | stop |

Tab. 1

In addition, there is also a toggle line, which must change its logical status every 40 ms if the table is activated. If there is no change within 100 ms, movement will stop. Each motor is encapsulated and water resistant. There is a limit switch for each end stop. In case of error, the entire drive must be replaced. In addition, micro switches S1, S2, S3, and S4 are available for the litho basic position.
A, B, C are equal-access plug-in positions on the table operating panel. They can be replaced for troubleshooting. 1, 2, 3 and 4 are the outputs for the motor. 5 and 6 are the limit switch inputs for the basic position.

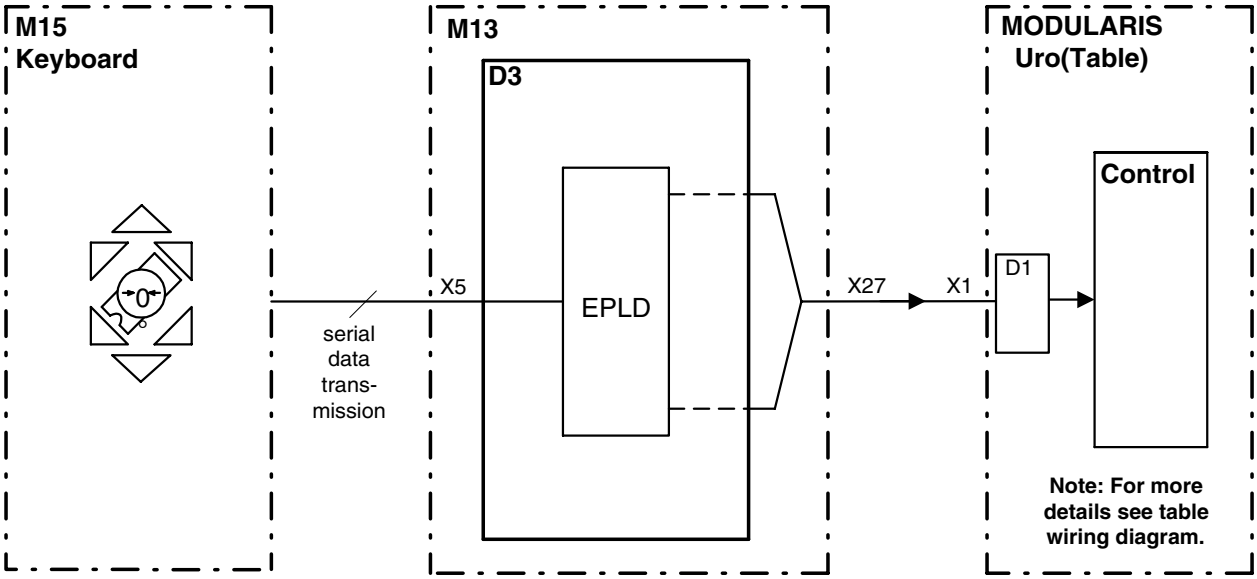



Fig. 4 Circuit diagram of table control with M15

**Circuit diagram:**

Measurement points:none

In case of function errors, first check the various controls (M15, tableside control or foot-switch) to determine whether it is an operating or motor function error.

## Circuit diagram

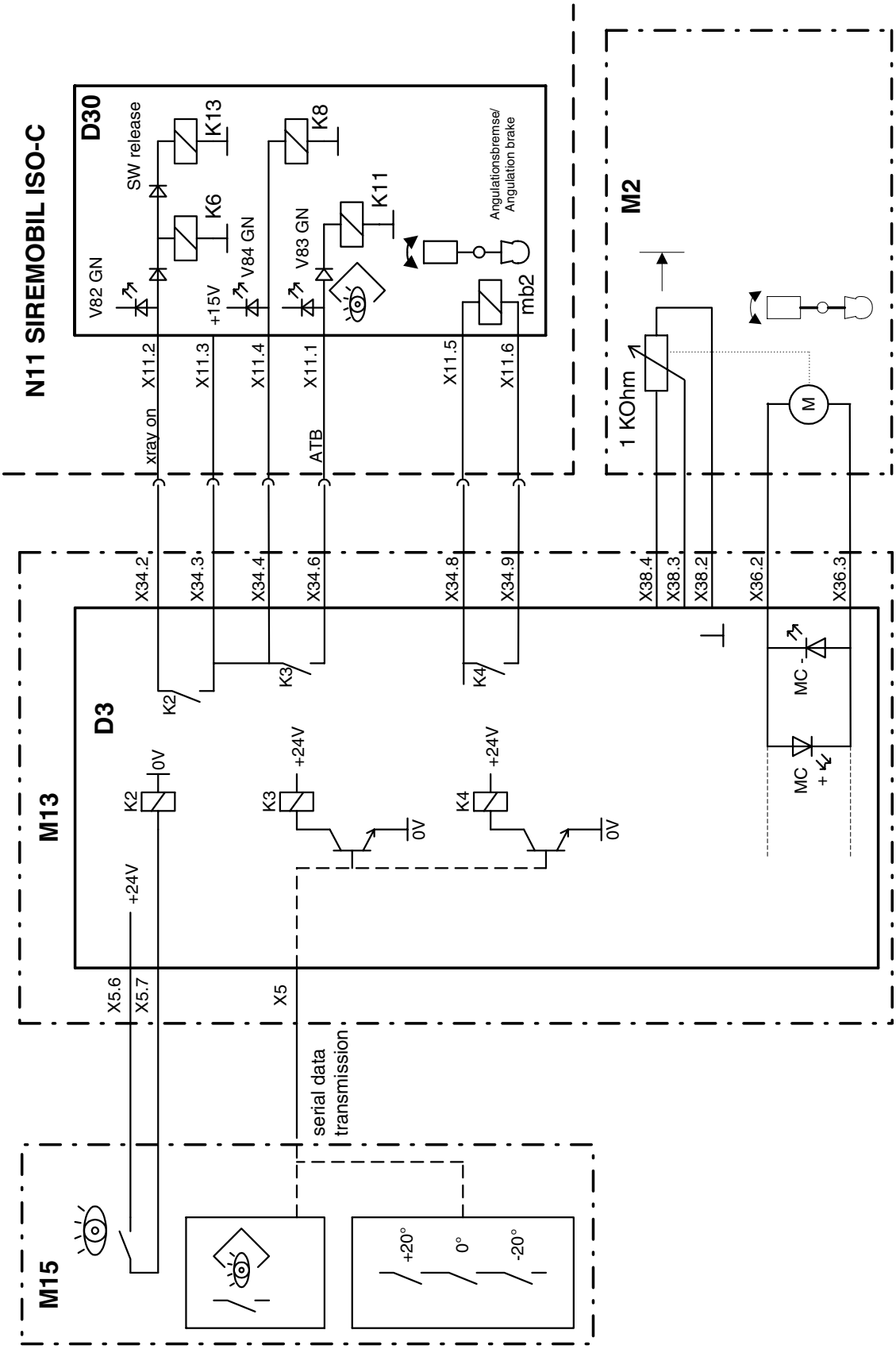



Fig. 1 Block diagram: ISO-C interface

**Docking mechanism:** Prior to docking the LITHOSTAR MODULARIS to the SIREMOBIL ISO-C, two micro switches were activated, which are not included in the block diagram (refer to ISO-C block diagram G5464 p.10/switch S4 and S.11/switch S3).
The switches block all brakes on the ISO-C. Moving the lifiting column is only possible after opening the docking bracket for decoupling.

**Start-up:** if the "X-ray on" key is pressed during start-up, a warning and error message will be transmitted. Shock wave release will be blocked until the key is released.

**Functions:**

**Radiation release:** The key on manual control **M15** is marked with a fluoroscopy symbol, but basically all available modes are usable. Software release signal **K13** and hand signal **K6** (dual protection) are activated via relay **K2** on board D30. **K8** deactivates the hand switch on the ISO-C.

**Save fluoro image: K3** responds, as well as **K11** on D30, whose contact activates the ATB (Auf Tastendruck Bild) function on control board D1 on the ISO-C.

**C-arm angulation (+20/-20°):** pressing the key releases the angulation brakes (via relay **K4**), and activates the angulation motor in **M2**. The µP on D3 receives an actual value position message from the 1 Kohm potentiometer. For purposes of testing, the angulation motor can also be checked in the uncoupled position. After switch-on, the brakes remain released until there has been motorized movement.

**C-arm adjustment:** adjustments are only possible in service mode. The movement velocity is reduced. When the adjustment mode is de-selected, the current actual value of the potentiometer is saved and used as the new mean position, as long as it is within the permissible tolerance range (short beep). Otherwise the default value will be used, and an error message will be transmitted (C-arm out of adjustment).

Default value 5V. Tolerance +/- 1.0 V.

## Goldcard system

When a goldcard system is started for the first time, a counter is activated and a code is set so that the card cannot be used in other systems. The card is checked during start-up and at specific intervals during operation. The user cannot see the Goldcard, i.e., no counter status and no messages with respect to the card.

## Pay per use system

The system can be started without the chip card. The card is checked during start-up or after insertion. Counter status is displayed in the main menu. The chip card can be ejected via the menu. During therapy, the counter status is decremented. When the chip card counter reaches less than 5000, a message is displayed, and the counter status flashes. If the user inserts a new card, all remaining units from the old card will be transferred to the new one.

The counter status is updated before the card is ejected.

### Service

Follow the specified procedure when replacing the D3 (PC 104) board (refer to Service Instructions).

### Chip card trace (available with future software versions)

A log of the last 50 chip cards in case:

...the chip card has an invalid status due to a defect, and the remaining units need to be calculated.

...the customer questions the units logged.

The following data is required, and can be called up with the service PC:

number of logged units, serial number of the card, number of units the last time it was ejected, date it was last ejected, and shot count for the system.

### The chip card interface

Serial interface RS 232. COM 1 of the PC 104 board is used and connected via flat cable to control board D3.
During system start-up and operation, a function test is performed. In case of error, the entire reading unit must be replaced.

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